DOI:
10.1002/jor.24235

Publication date:
2019

Research Article

The importance of locking plate positioning in proximal humeral fractures as predicted by computer simulations†

Running Title: Plate position affect fixation stability

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Author Contributions Statement:

All authors contributed to study design. PV acquired the data. PV, JWAF and MW interpreted the data. JWAF wrote the manuscript. PV, MW, RGR, BG and JB provided critical revision. All authors have read and approved the submitted version.

Conflict of interest statement

The authors have no conflict of interest.

†This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: [10.1002/jor.24235]

Received 12 September 2018; Revised 14 December 2018; Accepted 21 January 2019

Journal of Orthopaedic Research®

DOI 10.1002/jor.24235

Abstract

Multifragmented proximal humeral fractures frequently require operative fixation. The locking plates commonly used are often placed relative to the greater tuberosity, however no quantitative data exists regarding the effect of positional changes. The aim of the study was to establish the effects from variations in proximal-distal PHILOS humeral plate positioning on predicted fixation failure risk. Twenty-one left-sided low-density virtual humeri models were created with a simulation framework from CT data of elderly donors and osteotomized to mimic an unstable three-part malreduced AO/OTA 11-B3.2 fracture with medial comminution. A PHILOS plate with either four or six proximal screws was used for fixation. Both configurations were modelled with plate repositioning 2 and 4 mm distally and proximally to its baseline position. Applying a validated computational model, three physiological loading situations were simulated and fixation failure predicted using average strain around the proximal screws – an outcome established as a surrogate for cycles to failure. Varying the craniocaudal plate position affected the peri-implant strain for both four and six-screw configurations. Even though significant changes were seen only in the latter, all tests suggested that more proximal plate positioning results in decreased peri-screw strains whereas distalizing creates increases in strain. These results suggest that even a small distal PHILOS plate malpositioning may reduce fixation stability. Plate distalization increases the probability of being unable to insert all screws within the humeral head, which dramatically increases the forces acting on the remaining screws. Proximal plate shifting may be beneficial, especially for constructs employing calcar screws.

Keywords

Proximal humerus fracture, PHILOS plate, plate positioning, fixation failure, finite element analysis

Introduction

Locking plates have transformed the treatment of proximal humerus fractures, dramatically reducing complications. However, fixation failures continue to occur, being seen in approximately 20% of cases[1]. The biomechanics of proximal humerus plating are complex due to the specific bone characteristics and variations in patient anatomy. In decreased bone density, fixations fail mainly due to insufficient mechanical competence of the bone[2]. Additionally, the bone density within the humeral head exhibits considerable variation[3]. Reliable screw placement is needed in the areas where the bone competence and biomechanical benefits will be greatest. Given the fixed-angle design of some current proximal humeral plating systems, such as the PHILOS implant (DePuy Synthes, Zuchwil, Switzerland), accurate screw placement is dependent upon the position of the plate. However, consensus is lacking on what is the correct position[4]. Whilst the recommended PHILOS plate positioning in the surgical manual is 5-8 mm distal to the greater tuberosity[5], actual placement varies (Figure 1). Moreover, suggestions for ideal placement include a greater range of 5-10 mm distal to the superior edge of the greater tuberosity in anteroposterior (AP) view[6; 7]. In clinical practice, plates are positioned both more distal and more proximal than recommended, in part due to anatomical variations and operative challenges (Figure 1a). Whilst it has been reported that fixation failure can occur if plate or screw placement is inadequate[8-10], the effect of these variations on primary bone-implant stability still remains unquantified.

Plates must be positioned within a range insuring that they risk neither subacromial impingement by being too proximal, nor extraosseous calcar screw placement by being too distal (Figure 1a); hence, a compromise is needed. Surgical concerns seem to exist more with proximal positioning causing impingement than distal placement not allowing proper calcar screw insertion, perhaps because the former may be harder to disprove as a causative event if a patient has ongoing postoperative symptoms. The reported rate of subacromial impingement due to plate positioning and malunion is between 0 and 21.4%[11-14]. However, it is unclear what exactly constitutes clinically relevant post-operative plate impingement, as well as what percentage of postoperative patients can acquire active shoulder abduction necessary for subacromial impingement to occur. Reports of improvement in range of motion (ROM) following removal of plates can be difficult to interpret due to confounding factors related to arthrolysis and/or subacromial decompression that are likely to have been performed together with the metalwork removal.

The aim of this study was to assess the effects of variations in proximal-distal PHILOS plate positioning on predicted fixation failure risk using a validated osteosynthesis test kit[15; 16]. We hypothesized that variations in plate positioning would generate quantifiable differences in predicted failure risk.

Methods

Finite element (FE) models of osteotomized and plated proximal humeri were created with a previously established simulation framework[16]. This virtual osteosynthesis test kit incorporates a database of digital bone samples, fracture models, implants and loading schemes, as well as a validated FE simulation methodology[15] to investigate and improve fixation stability. In this study, twenty-six, left-sided, low-density humeri from 14 female and 12 male elderly donors (mean ± standard deviation (SD) age 83.9 ± 8.1 years (range 64 – 98 years)) were selected from the digital sample collection of the test kit. Bone mineral density (BMD) was evaluated via the method of Krappinger et al.[17] using high-resolution peripheral quantitative computer tomography (HR-pQCT, XtremeCT, Scanco Medical AG, Brüttisellen, Switzerland) images of the bones. Median BMD was 107.4 HAmg/cm^3, with a range of 68.9

– 129.6 mg/cm^3. Low density samples were chosen as these represent the greatest surgical challenge. The humerus models were osteotomised to create an unstable three-part malreduced fracture AO/OTA 11-B3.2 with medial comminution – defined as gapping between the fragments – and were virtually fixed with a PHILOS plate. The plate was positioned as per the surgical technique guide[5], using virtual Kirschner wires and targeting blocks to ensure correct placement for its baseline neutral position (Figure 1b).

Five different plate positions were investigated: the baseline position as defined according to the recommendations in the surgical guidelines[5], as well as positions with proximal shifts of 2 mm and 4 mm, and distal shifts of 2 mm and 4 mm relative to the baseline position. Two different clinically relevant screw configurations were chosen for analysis, one with four screws (inserted into rows A and B of the plate; mimicking the minimally invasive operative technique using a percutaneous aiming system) and a second with six screws (using rows A, B and E; comprising the 4-screw configuration plus the two calcar screws) (Figure 2). For both configurations, the selection criteria of the samples required that the tips of all proximal screws were contained within the humeral head in all plate positions. Screws were inserted at 6 mm distance from the subchondral surface (tip-joint distance (TJD)). Non-commercial screws lengths were implemented to ensure that the TJD remained constant regardless of anatomy. The FE models were meshed with tetrahedral elements using Simpleware v7.0 (Simpleware Ltd., Exeter, UK) with a previously determined appropriate mesh density[15]. Material properties, including BMD-based stiffness assignment for bone elements, and interface models were taken from a previous validation study[15]. The models were loaded in three physiological loading cases – 45° abduction with 0° internal rotation, 45° abduction with 45° internal rotation, and 45° flexion with 0° internal rotation – where the joint and muscle forces were sourced from musculoskeletal simulations performed with Anybody software (v5.0, AnyBody Technology A/S, Aalborg, Denmark). The FE analyses were run in Abaqus v6.13-3 (Simulia, Dassault Systemes, Velizy-Villacoublay, France) and the average bone strain within cylindrical regions around the proximal screws tips was evaluated. This strain was reported to be an authenticated surrogate measure for prediction of biomechanical cyclic fixation failure[15]. All pre-processing, analysis and post-processing methods used had been previously established[15; 16].

Statistical analysis was performed with the use of ‘R’ v3.3.3 (R Foundation for Statistical Computing)[18]. Effects from plate repositioning were compared by averaging the strain around all proximal screw tips for the respective construct and summating the values from the three loading modes. For these comparisons, each shifted plate position was compared to the baseline position and to every other position, with the Related-Samples t-test or Wilcoxon Signed-Rank test depending on the normality of distribution as checked with the Shapiro-Wilk test. Following, individual screw strains and lengths were analyzed to screen for changes when the plate was shifted, comparing repositioned plates to their baseline positions. Statistical significance was defined as $p<0.05$ with Bonferroni corrections for multiple comparisons.

Results

Five (19%) humeri models were excluded as at least one of the calcar screws (row E) was not sited within the humeral head in all configurations. All analyses were performed with the remaining 21 samples. Plate position affected the distribution and magnitude of the deformation in the trabecular bone region around the screw tips for both four and six-screw constructs (Figure 3).

For the six-screw configuration, both 2 and 4 mm shifts generated significant ($p<0.001$) changes in average peri-screw bone strains in comparison to the baseline neutral position; proximal shifts reduced strains (for 2 and 4 mm shifts, $p=0.0008$ and 0.00005, respectively), whilst distal movement increased them ($p=0.00074$ and 0.00001, respectively) (Figure 4). With four proximal screw configurations, mild trends toward increased strain with distal shifts of the plate and decreased strain with proximal shifts were observed; however, all comparisons between the plate positions were of non-significant. The average strain values of all screws were significantly lower in the six-screw configuration compared to the four-screw configuration for each plate position ($p=0000001$, 0.000002, 0.000064, 0.000064 and 0.000001 for distal 4 mm, distal 2 mm, baseline, proximal 2 mm and proximal 4 mm positions, respectively).

The change in the individual peri-screw bone strains with shifted plate positions is illustrated in Figure 5, showing that, when comparing changes in strains around the same screw between different plate positions, an increase in strain values occurred for most of the screws after distal plate movements in the six-screw configurations only. Reciprocally, decreased strains in six-screw configurations were found after proximal plate movements. The changes in strains after both distal and proximal plate movements were significant only for the four most proximal screws within the six-screw construct ($p<0.001$).

There were significant ($p<0.001$) changes in average screw lengths when shifting the plate compared to the baseline position (Figure 6), with shorter screws being seen as plates were positioned more proximally (for the four-screw configuration: $p=3.9E-16$, 3.5E-16, 1.1E-17 and 1.6E-12 for distal 4 mm, distal 2 mm, proximal 2 mm and proximal 4 mm positions, respectively; for the six-screw configuration: $p=0.00087$, 2.4E-07 and 7.9E-09 for distal 2 mm, proximal 2 mm and proximal 4 mm positions, respectively), except for the 4 mm distal position for the six-screw configuration that was not different compared to baseline. When considering individual screws lengths, with distalization of the plate the calcar screws significantly ($p<0.001$) shortened, with reciprocal lengthening of the most proximal screws. With proximal plate movement, there was significant shortening of the proximal screws, though non-significant increases in calcar screw lengths. This proximal screw shortening (Figure 6) was not associated with weaker constructs in the four-screw configuration but was associated with decreased peri-screw strains in the six-screw configuration (Figure 4).

Discussion

Plate positioning was found to affect predicted peri-screw bone strains considerably in the presence of calcar screws (six-screw configuration), with increases occurring with distal plate movement and decreases with plate proximalization. Additionally, a similar, though non-significant, trend was observed when plates without calcar screws were repositioned (four-screw configuration). Given that peri-screw strains have been shown to correlate with cut-out type fixation failure risk, it can be deduced that distalization of the six-screw configurations increases failure risk whilst proximalization could be beneficial. Compared to the four-screw constructs for the equivalent plate positions, the presence of calcar screws generated decreases in average peri-screw strains (Figures 3 and 4).

Why computer simulations?

By utilizing computer simulations to investigate these clinical scenarios, this study's methodology allows for the unique detection of findings otherwise potentially obscured due to the additional variables seen in either clinical or biomechanical studies. Computational modelling of variations in plate position offers significant benefits over these alternative methods due to the number of cases that can be tested; such numbers being financially and ethically prohibitive in biomechanical studies. Furthermore, a substantial variable in comparison studies relates to patient anatomy. Pairwise comparisons have been shown to exhibit substantial differences in bone density and anatomy[19]. In our study, computer simulations allowed plate, and thus screw, positions to be investigated individually, without bias being introduced through uncontrolled changes in other known variables, such as fracture type, quality of reduction or loading modes. For example, screw tip position always remained constant at a 6-mm distance from the subchondral surface. Whilst this meant that non-commercial screw lengths were modelled, it ensured that variations in screw tip position would not introduce a further variable to the testing; this could not have been controlled in biomechanical or clinical testing.

Comparison with previous studies

Metha et al. performed a biomechanical study using cadaveric and artificial humeri to assess the effects of locking plate positions[20] at three different sites, neutrally (calcar screws 3 mm proximal to the apex of the inferior humeral head arch), +8 mm and -8 relative to this, with relatively simple, 2-part fracture configurations being tested. No significant differences between the three plate positions were found in cadaveric specimens in terms of stiffness, torsion or displacement following cyclic loading; however, with proximally positioned constructs, non-significant trends towards less displacement were found following cyclic testing. Nevertheless, contradicting the findings from the present study, Mehta et al. suggested that distal plate placement may be beneficial. From a retrospective clinical analysis, Padegimas et al., reviewing 161 patients with 2, 3 and 4-part fractures, found that if screws intended to engage calcar bone were placed more than 12 mm proximal to the apex of the inferior humeral head arch, higher failure rates were be observed; calcar screws in fracture fixations that failed were located considerably more proximal (19.2 vs 9.5 mm proximal to the arch apex)[21]. However, in poorly reduced fractures, more reflective of the conditions analyzed in our study, their results did not clearly show this. Furthermore, screws positioned more proximal than 12 mm may have been sufficiently far away from the calcar to be ineffective as they were outside of the calcar region. We have shown that within the calcar region (±4 mm) it is the distalization that increases failure risk (Figure 5). Those studies being not fully conclusive may be explained by the variations of factors that have been overcome in this study via systematic computer analysis of the isolated effect of plate positioning as described above. Nevertheless, our results may be specific to cut-out type fixation failures.

Importance of calcar screws

When calcar screws were used, their peri-screw strains increased with plate distalization, yet after plate proximal movement the strains did not change considerably compared to the baseline values (Figure 5). In the six-screw constructs, the proximal four screws all showed significant reductions in peri-screw strains after proximal movements, and increases seen after plate distalization. The explanation postulated to be by the presence of calcar screws in a more proximal part of the humeral head shielding the proximal screws (rows A and B) from greater deforming forces compared to more distal calcar screw positions. This may, in part, be explained by the ability to insert longer calcar screws when the plate is more proximally positioned, and/or by the presumption that more of the calcar screw threads are located in the fracture fragments and/or in higher density bone, though these aspects were not investigated in the current study. The importance of calcar screws has been shown biomechanically and computationally in previous studies[22-24], and retrospectively in clinical reviews[21]; this study's findings add to their justification by showing that these screws directly and indirectly support the function of other screws within the constructs. These findings could encourage surgeons to prioritize the placement of calcar screws over others, given their dominant role in reducing failure risk. However, their significant effect may be limited to unstable fractures that have no medial support, like those simulated in this study.

Effect of screw length

The volume and density of bone available for purchase will affect the forces encountered by the screws and the plate. Due to its fixed-angle design, plate positioning dictates the trajectories of screw insertion, with the anatomy and curvature of the humeral head then prescribing the lengths of the screws that can be used. Indeed, only variations in plate position were responsible for changes in average screw lengths through changes in the bone available for each screw hole trajectory, as the TJD was always constant. To some extent, it is logical to think that longer average screw lengths within a construct could reduce average peri-screw strains due to more bony purchase being available, assuming that the fracture configuration allows for more screw threads to gain purchase in each fragment. However, our results revealed no correlation between greater average screw length and reduced average peri-screw strains. Moreover, reduced peri-screw strains were seen when average screw lengths shortened. This reduction in average screw length, associated with proximal plate positioning and no increase in peri-screw strains, potentially highlights the assumption that the locations, rather than the average lengths of the screws, seem to be more critical for fixation stability. However, whilst average screw lengths may not be critical, specific individual screw lengths may be. With proximal movement of the six-screw construct, whilst average screw lengths decreased and the most proximal screws (row A) significantly ($p<0.001$) shortened, the calcar screws (row E) non-significantly lengthened, which was associated with reduced predicted failure risk. Whilst the TJD was kept constant, there was no assessment of the proportion of screw threads within the medial humeral head fragments, which may be more important for anchorage than the screw lengths themselves. Bone density does vary in different regions of the humeral head[3], and may also be partially responsible for the changes seen in the strain of individual screws and the purchase they gained in different areas. There may be some surgical concerns that proximalizing the plate to ensure good calcar placement requires reducing the length of its proximal screws. However, our results have shown that shorter proximal screws do not lead to increases of their peri-screw bone strains or the averaged strain over the whole construct.

Impingement risk versus missing the calcar screws

Proximalization of humeral plates raises concerns about mechanical impingement with shoulder movements, especially on abduction. Conversely, distalization may result in an inability to place calcar screws inside the humeral head. Investigations into these factors have had varied results. Thienthong et al. positioned plates in 30 cadaveric shoulders at the level of the proximal bicipital groove and did not report any passive impingement[25], whereas more distal positioning of 30 contralateral plates at the level of the lesser tuberosity prominence resulted in distal screw perforation in 87% of cases. Interestingly, even with the proximal positioning in 30 of these cases, two still resulted in calcar perforation. Whilst their study assessed passive subacromial impingement, it shows the narrow margin that some patients' anatomies allow regarding calcar screw placement. We have shown that even a distal shift of 4 mm from the recommended position resulted in 19% of the humeri being unable to receive at least one of the calcar screws. Other biomechanical studies have encountered this problem with calcar screw insertion, with varied interpretations of the potential consequences. Extraosseous screw placement will reduce fixation potential due to the screw threads not being engaged to provide resistance to shear motion. However, it has been suggested that they may act as a buttress to varus collapse; Mehta et al. used the LCP proximal humeral plate with three proximal screws and found that the buttress provided by calcar screws increased initial construct stiffness[20].Their results did not show proximal positioning resulting in any reported impingement but did show distal positioning causing occurrences of calcar screw perforation and a non-significant trend towards more displacement with cyclic loading.

Achieving the desired plate position clinically

To aid accurate screw placement, targeting devices are provided with the PHILOS surgical kit and were used in the positioning of plates in this study[5]. Here a targeting block is attached to the proximal aspect of the plate to enable using of a Kirschner wire as a reference to the dome of the humeral head. Further to this, more advanced targeting aids have been developed, using the real-time plate location to predict the screw positions and lengths that can be used[26]. Until these devices become available on the market, we recommend using the current targeting Kirschner wire and prioritizing calcar screw placement first, then referencing the plate position to these before proximal screw insertion, even if this requires proximalization of the plate and shorter proximal screws. Further work into the effects of different screw configurations would help corroborate this advice.

Limitations

This study is computational, and though well validated, is ultimately limited by the accuracy of the model and may not exactly mimic all clinical situations. The findings are also restricted to fixation stability and modelling a cut-out type failure and do not consider other effects, such as secondary screw perforation. Our findings may be restricted to being only relevant for the malreduced unstable three-part fracture model investigated here. While this represents a clinically challenging scenario especially regarding the missing medial support, our findings may not apply to the even more complex unstable four-part fractures. No assessment of potential impingement was considered, though the clinical relevance of this has already been questioned. The loading modes modelled attempt to replicate movements exhibited by patients in the early postoperative phase, though they will not characterize the activities of all patients. However, using three loading modes exceeds the quantity and quality of conditions applied in other modelling and biomechanical studies[22; 27]. Only left sided bones were investigated while the PHILOS plate exhibits an asymmetric screw pattern. Even though unlikely, a different finding in right specimens cannot be excluded. Whilst the statistical analysis combined the strain values for all three loading modes to increase the generalizability of the findings, this may have overlooked smaller changes occurring after specific movements. No assessment of the effects from tilting the plate nor from changes in plate elevation were considered. However, proximal humeral anatomy greatly limits the range of alternative plate positions available, hence only craniocaudal positional differences were studied. Virtual subjects with lower bone quality were selected for modelling in this study; the failure risk with plate movement in patients with higher bone density may be different. There may have been considerable benefits from proximalizing four-screw constructs, however, the greater average and variation of the strain values for these constructs may have prevented the detection of those significant changes; the same trends were seen with the six-screw construct, but at significant levels (Figures 3 and 4). Additionally, it is advised by the surgical guide[5] that in patients with poor bone stock even more screws should be used, i.e. all nine proximal screws, neither six nor four. The basis of this advice can be seen in the reduction of the average screw strain by adding calcar screws to the constructs.

Conclusions

Distal PHILOS plate positioning resulted in an increased risk of cut-out type failure in our virtual cases. This study demonstrated that even small distal malpositioning of the plate may decrease fixation stability of unstable 3-part fractures in low density humeri, whilst proximal shifting of the plate may be beneficial. These findings were most prominent for the six-screw configuration. Furthermore, regardless of the plate position, utilizing calcar screws significantly reduces peri-screw strains around the other screws. Whilst these findings require clinical validation through longitudinal observational studies, they suggest that plate placement should be performed carefully with calcar screw placement being prioritized.

Acknowledgements

The authors are not compensated and there are no other institutional subsidies, corporate affiliations, or funding sources supporting this work unless clearly documented and disclosed. This study was performed with the assistance of the AO Foundation via the AOTRAUMA Network (Grant No.: AR2013_01).

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Figure captions

Figure 1 Positioning of the PHILOS plate to fix proximal humerus fractures in clinical cases (A) may deviate from the alignment suggested by the surgical guide. This advises the use of a guiding block and a K-wire, which was virtually reproduced in this study to define the baseline models (B).

Figure 2 The effect of plate positioning was assessed by 2 mm and 4 mm shifts proximally and distally with respect to the baseline. These analyses were repeated for a four-screw (screws rows A and B) and a six-screw (screw rows A, B and E) configurations.

Figure 3 Contour plots of the compressive principal strain distribution in a sagittal section, illustrating higher bone deformations for the four-screw configuration versus the six-screw construct and, for the latter, indicating the increase and decrease of the strain magnitudes with distal and proximal plate shifts, respectively.

Figure 4 Average compressive principal strains in the bone region around the screw tips show a non-significantly incising trend with distal plate shift in the four-screw construct. The same trends become clearly significant (* indicates $p<0.05$) for the six-screw configuration and here a more proximal plate position is associated with a decreased peri-implant strain and thus a reduced fixation failure.

Figure 5 Average bone strains around the individual screws are, in general, not significantly changing in the four-screw configuration when shifting plate. These results are more sensitive for the plate position in the six-screw construct.

Figure 6 Screw length shows a clearly increasing trend in the four-screw configuration (left) when shifting the plate from distal to proximal. In the six-screw construct (right), the length of the calcars screws is decreased by the proximal plate positioning, resulting in a less clear trend for the average screw length.

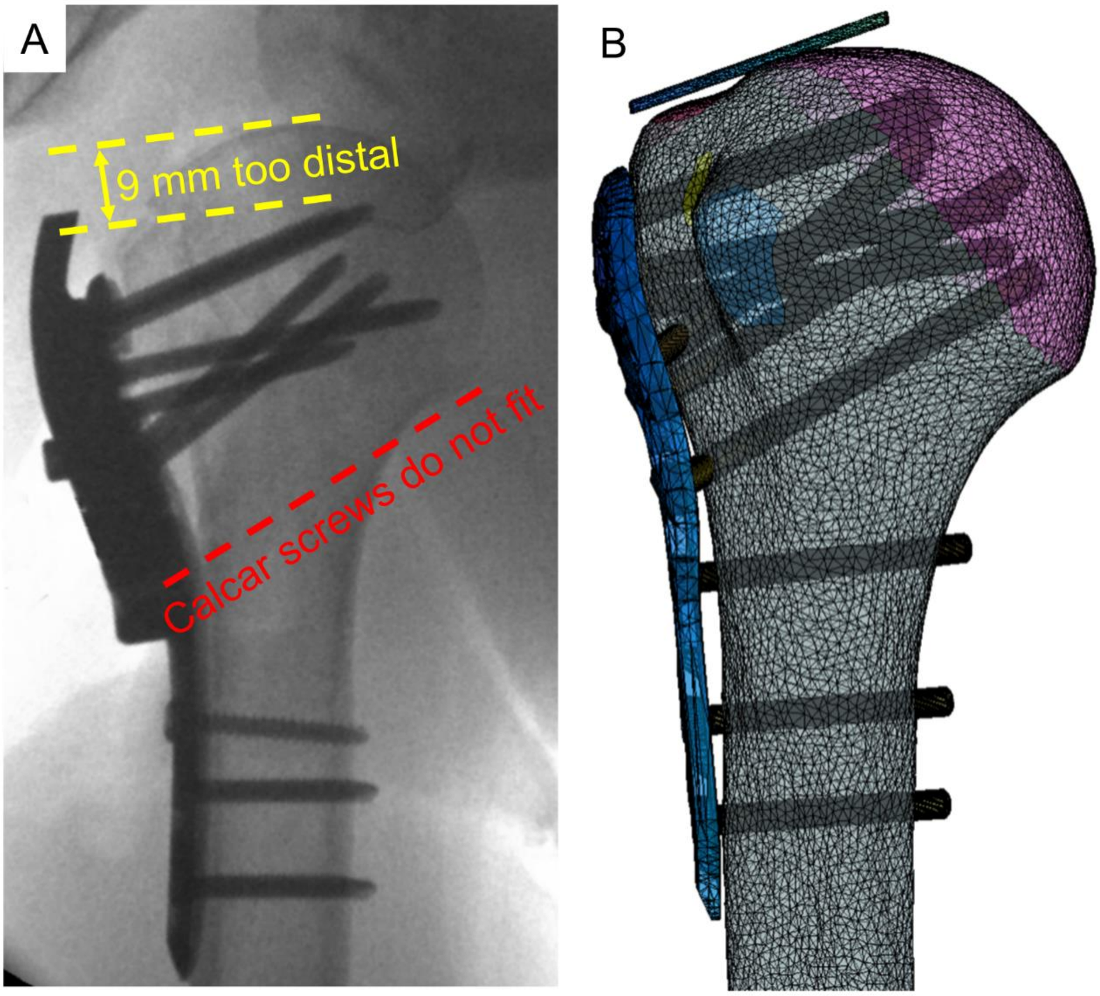


Figure 1

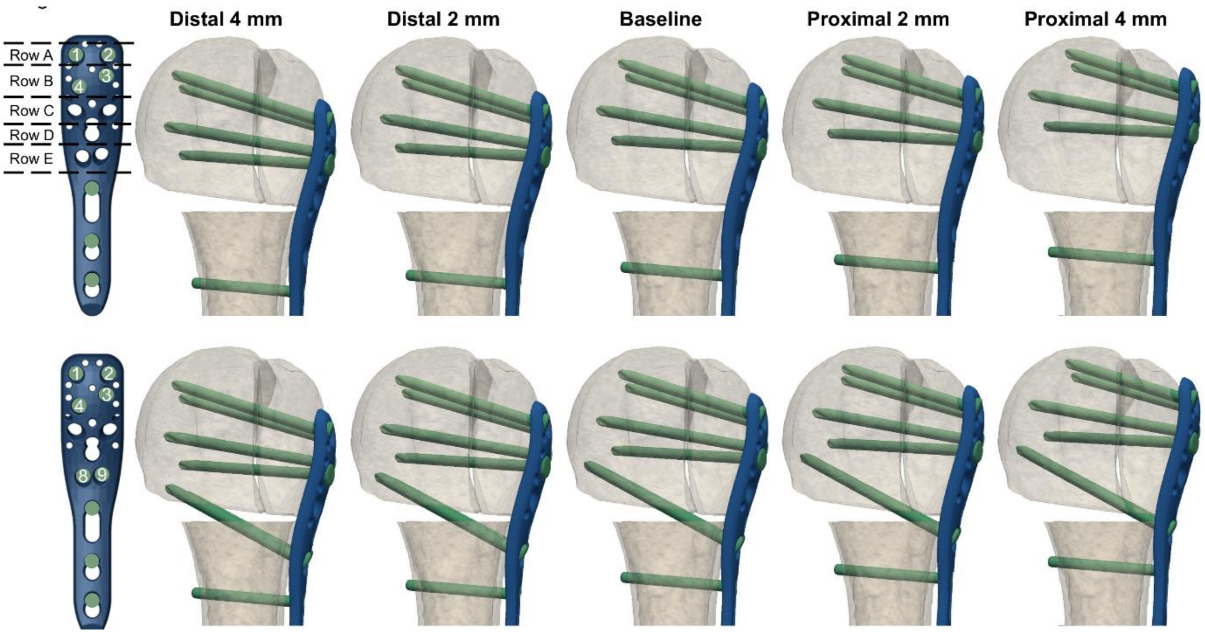

Distal 4 mm
Distal 2 mm
Baseline
Proximal 2 mm
Proximal 4 mm
Row A
Row B
Row C
Row D
Row E
1
2
3
4
8
9

Figure 2

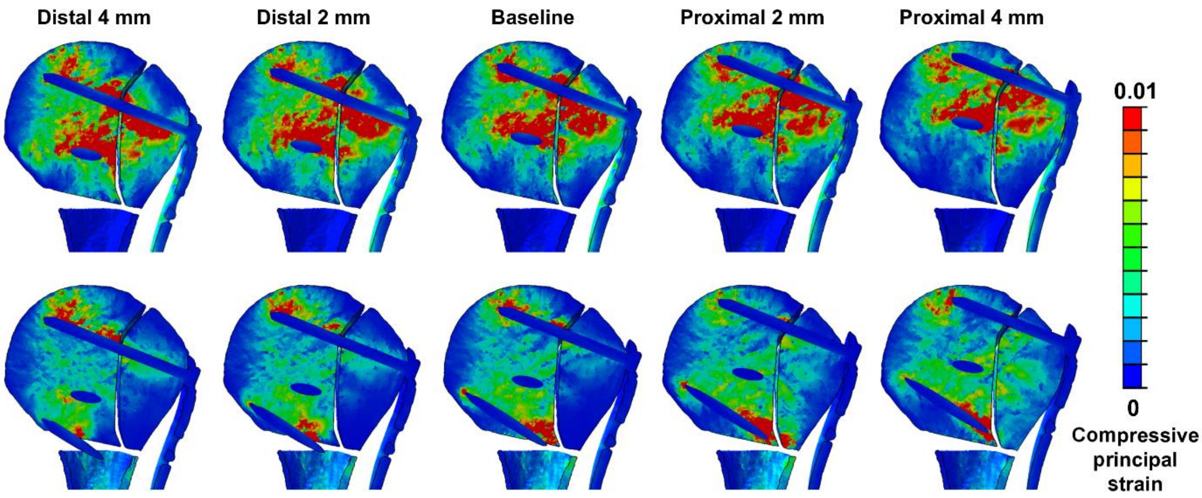
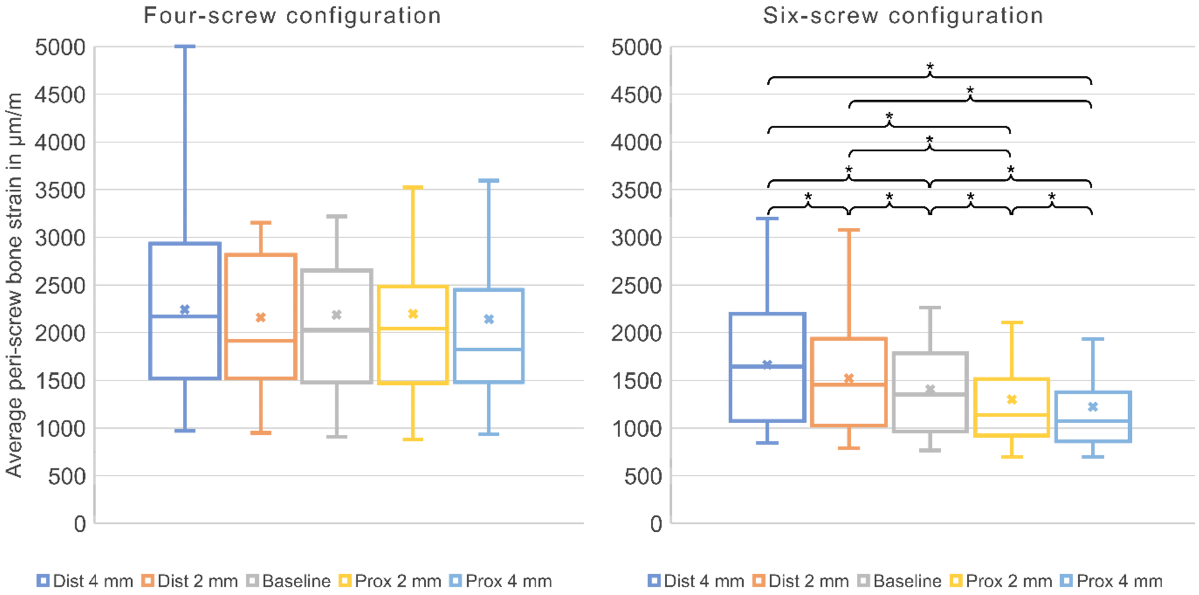

Distal 4 mm
Distal 2 mm
Baseline
Proximal 2 mm
Proximal 4 mm
0.01
0
Compressive principal strain

Figure 3



Four-screw configuration
Six-screw configuration
Average peri-screw bone strain in µm/m
5000
4500
4000
3500
3000
2500
2000
1500
1000
500
0
*
Dist 4 mm
Dist 2 mm
Baseline
Prox 2 mm
Prox 4 mm

Figure 4

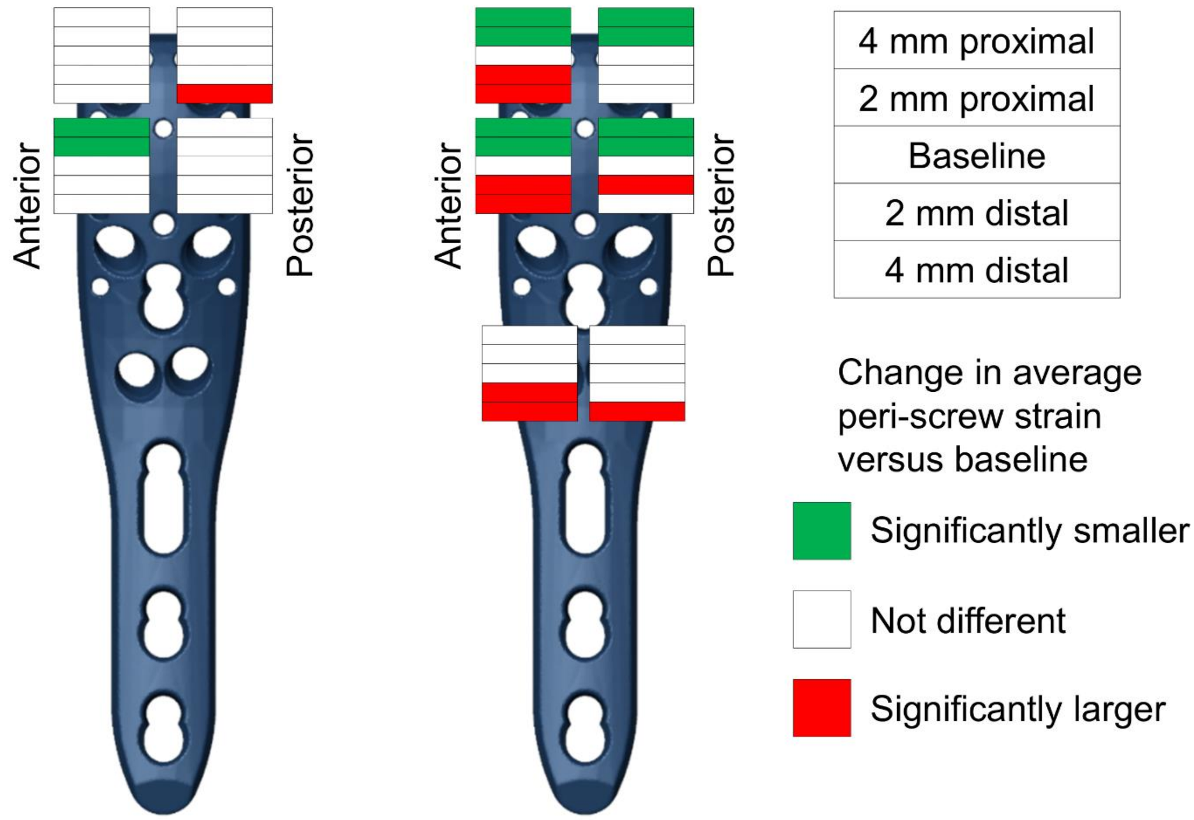
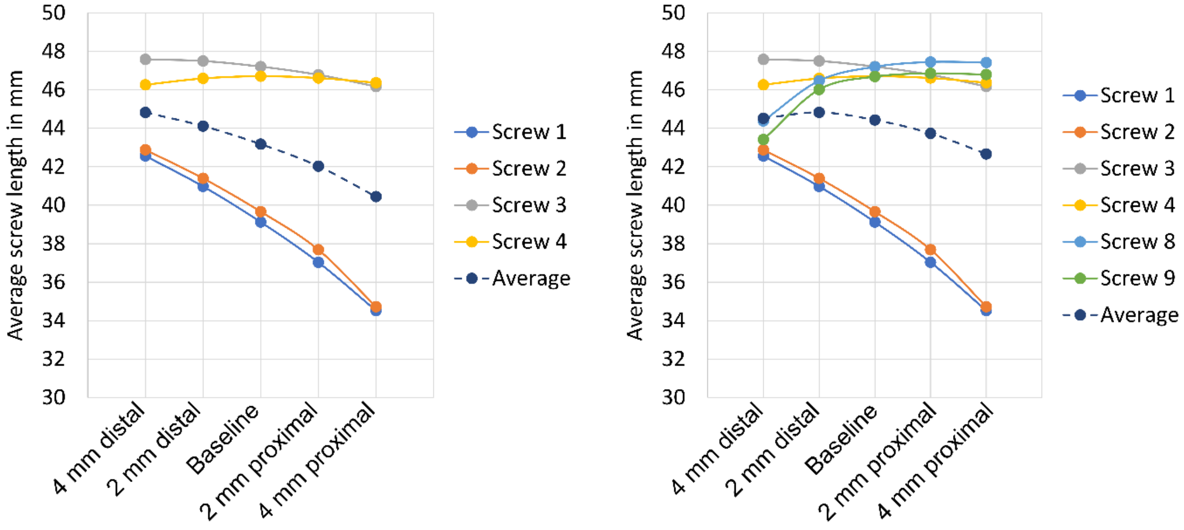

Anterior
Posterior
Anterior
Posterior
4 mm proximal
2 mm proximal
Baseline
2 mm distal
4 mm distal
Change in average peri-screw strain versus baseline
Significantly smaller
Not different
Significantly larger

Figure 5



Average screw length in mm
50
48
46
44
42
40
38
36
34
32
30
4 mm distal
2 mm distal
Baseline
2 mm proximal
4 mm proximal
Screw 1
Screw 2
Screw 3
Screw 4
Average
Average screw length in mm
4 mm distal
2 mm distal
Baseline
2 mm proximal
4 mm proximal
Screw 1
Screw 2
Screw 3
Screw 4
Screw 8
Screw 9
Average

Figure 6